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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,357	03/21/2001	De-Chao Yu	348022001600	3927

24353 7590 05/12/2004

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

289-
Office Action Summary

Application No.

09/814,357

Applicant(s)

YU ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/23/04.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 77-85 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 77-85 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 77-85 are pending.

Applicants' traversal, the amendment to claim 77, and the cancellation of claims 1-76 in paper filed 2/23/04 is acknowledged and considered.

However, the amendment to the specification filed on 2/23/04 was not entered because the amendment to the specification was not in compliance with revised 37 CFR 1.121. The amendment to the specification must begin on a separate sheet.

Specification

The disclosure remains objected to because of the following informalities: The disclosure is objected to because of the following informalities: page 117 recites, "Figure 613." There is no Figure 613.

Appropriate correction is required.

When filing the amendment to this instant action, applicants are reminded to follow the revised amendment practice 37 CFR 1.121. See 68 Fed. Reg. 38611 (June 30, 2003) or website <http://www.uspto.gov/web/patents/ifw/>.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 77-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 77 filed on 2/23/04 introduces new subject matter into the application.

The application and the originally filed claim as a whole are directed to:

A method for method for suppressing tumor growth in a mammal comprising: administering a synergistic combination of a replication competent, target cell-specific adenovirus, said adenovirus comprising an adenoviral gene essential for replication under transcriptional control of a prostate-specific antigen (PSA)-TRE wherein said target cell-specific adenovirus results in virus replication-dependent cytolysis; and at least one antineoplastic agent selected from the group consisting of etoposide, estramustin, paclitaxel, docetaxel and doxorubicin, in a combined dosage effective to substantially reduce the numbers of said targeted solid tumor cell population, wherein said tumor growth is suppressed.

The original specification did not disclose: A method for suppressing tumor growth in a mammal comprising: administering to a mammal a synergistic combination of a replication competent, target tumor cell-specific adenovirus, said adenovirus comprising an adenoviral gene essential for replication under transcriptional control of a prostate-specific antigen (PSA)-TRE wherein said target tumor cell-specific adenovirus results in virus replication-dependent cytolysis; and at least one antineoplastic agent selected from the group consisting of etoposide,

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estramustin, paclitaxel, docetaxel and doxorubicin, in a combined dosage effective to substantially reduce the numbers of said targeted solid tumor cell **population to a level more than additive when compared to administration of the adenovirus vector and antineoplastic agent alone**, wherein said tumor growth in said mammal is suppressed.

The pages cited (Table 5, Figures 3-8 and 27) for support of the added limitation to claim 77 do not support the added limitation. The Table cited is directed to *in vitro* results and not *in vivo* results. Figures 2-9 are directed to *in vitro* results. The only Figure cited by applicants with *in vivo* results is Figure 27 (CV787 and estramustin). However, Figure 27 does not display a synergistic effect for the combination. Figure 23 and Figure 28 are the only Figures that provide support for using CV787 and an antineoplastic agent in a synergistic combination *in vivo*, wherein the agent is selected from taxol (paclitaxel) and taxotere (docetaxel). The specification does not provide written support for using etoposide, estramustin and doxorubicin in the claimed method. It is apparent that the applicants at the time the invention was made did not intend or contemplate the claimed method as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the method for suppressing tumor growth in a mammal using CV787 and etoposide, estramustin and doxorubicin in a synergistic combination as set forth in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Response to Arguments

Applicant's arguments, filed 2/23/04, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claims 72-74 and 77-83 has been withdrawn because of the cancellation of claims 72-74 and the amendment to claim 77.

Applicant's arguments, filed 2/23/04, with respect to the rejection(s) of claim(s) 62, 63, 72, 73, 77-82, 84, and 85 under 103(a) over Henderson taken with Gurnani have been fully considered and are persuasive. Therefore, the rejection of claims 62, 63, 72, 73, 77-82, 84, and 85 has been withdrawn because of the cancellation of claims 62, 63, 72, and 73 and the amendment to claim 77.

Applicant's arguments, filed 2/23/04, with respect to the rejection(s) of claim(s) 73, 74, 77, 80, 82 and 83 under 103(a) over Henderson taken with Gurnani in further view of Duque have been fully considered and are persuasive. Therefore, the rejection of claims 73, 74, 77, 80, 82 and 83 has been withdrawn because of the cancellation of claims 73 and 74 and the amendment to claim 77.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER